

REMARKS

Reconsideration and reexamination of the present application are respectfully requested in light of the foregoing amendments and following remarks.

The amendments are made without prejudice or disclaimer of the canceled subject matter. Applicants reserve the right to file a continuing or divisional application on any subject matter canceled by way of amendment.

1. Status of the Claims

Claims 11-12, 14-16, and 19 stand pending. Claims 1-10, 13, 17-18, and 20-21 are canceled.

2. Support for the Amendments

(i) In claims 11, 12, and 15, "R' is an optionally substituted phenyl group" is replaced with "R' is a phenyl group optionally substituted with a substituent selected from the group consisting of a halogen atom, a hydroxyl group, a C1-C5 optionally branched alkoxy group, and a C1-C5 optionally branched alkyl group optionally substituted with a halogen atom." Support for this amendment can be found, for example, at page 11, lines 10-19, of the Specification.

(ii) In claims 11, 12, and 16, "R' is . . . an optionally substituted phenoxy group" is replaced with "R' is . . . a phenoxy group optionally substituted with a substituent selected from the group consisting of a halogen atom, a hydroxyl group, a C1-C5 optionally branched alkoxy group, and a C1-C5 optionally branched alkyl group optionally substituted with a halogen atom." Support for this amendment can be found, for example, at page 11, lines 10-19, of the Specification.

(iii) In claims 11, 12, and 14, "R' is . . . an optionally substituted benzoyl group" is replaced with "R' is . . . a benzoyl group optionally substituted with a substituent selected from the group consisting of a halogen atom, a hydroxyl group, a C1-C5 optionally branched alkoxy group, a C1-C5 optionally branched alkyl group optionally substituted with a halogen atom." Support for this amendment can be found, for example, at page 11, lines 10-19, of the Specification.

Finally, the word "that" is inserted in sixth line from the bottom of claim 11 for grammatical clarity.

3. Double Patenting Rejection

The rejection of the claims 11, 12, 14-16 and 19 is maintained over (1) U.S. Patent No. 6,455,549, issued from U.S. Application No. 09/043,563 ("the '549 patent") and (2) U.S. Patent No. 6,838,470 ("the '470 patent") under the judicially created doctrine of obviousness-type double patenting.

(1) The '549 patent.

Applicants file herewith a Terminal Disclaimer that disclaims the term of a patent issuing from the instant application that extends beyond the expiration of the '549 patent. As indicated in the Terminal Disclaimer, the instant application and the '549 patent are commonly owned by Asubio Pharma Co., Ltd. In this context, Applicants refer to the Change of Name, filed May 23, 2007 in the instant application, which indicates a change of name from "Daiichi Asubio Pharam Co., Ltd." to "Asubio Pharma Co., Ltd." The assignment history of the '407 patent evidences the assignment recorded May 29, 2007, which transferred ownership of the '407 patent to Asubio Pharma Co., Ltd. The rejection accordingly should be withdrawn.

(2) The '470 patent.

(i) The Office does not meet the legal standard for establishing a *prima facie* case of obviousness

The presently pending claims are rejected as allegedly obvious over claims 1-10 of the '470 patent. The Office alleges that the two sets of claims contain overlapping subject matter. Office Action mailed January 11, 2006, pages 3-5. Applicants responded that the structure of Formula (I) of the '470 patent differs from the compound of Formula (I') of the present claims. Amendment and Reply Pursuant to 36 C.F.R. § 1.111, pages 4-5. The Office responded with an improper conclusory allegation that the subject matter of claims 1-10 of the '470 patent "has similar and obvious modifications of the subject matter [of the present claims]." Final Office Action mailed October 11, 2006, pages 2-3. Applicants responded by pointing out the conclusory character of the Office's remarks. Reply Pursuant to 37 C.F.R. § 1.116, pages 3 and 5. Applicants further pointed out that that the instant application, if issued, would expire prior to the expiration of the '470 patent, and that a Terminal Disclaimer is thus unwarranted. *Id.*, page 5.

In the Advisory Action, page 4, the Office alleges—without providing evidence—that claims 1-10 of the ‘470 patent contain subject matter that overlaps with the present claims. The Office cites *KSR Int’l Co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385 (2007) for the proposition that the Federal Circuit’s teaching, suggestion, or motivation test should not be applied as a rigid formula, and that the fact finder should include market demand in the *Graham v. Deere* obviousness analysis.

Whether a claim is obvious is based on an objective analysis of the scope and content of the prior art, the differences between the prior art, or in this case the claims of the ‘470 patent, and each element of the claimed invention, and the level of skill in the pertinent art. *See Graham v. John Deere Co.*, 383 U.S. 1, 15-17 (1966); *see also* M.P.E.P. § 804. The Office’s objective analysis of obviousness should be made explicit. *See KSR*, 82 U.S.P.Q.2d at 1396; *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”). The factual inquiry whether to combine references must be based on objective evidence of record. *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (“This precedent has been reinforced in myriad decisions, and cannot be dispensed with.”). In short, the factual question of motivation cannot be resolved on the basis of subjective belief. *Lee*, 277 F.3d at 1343-44.

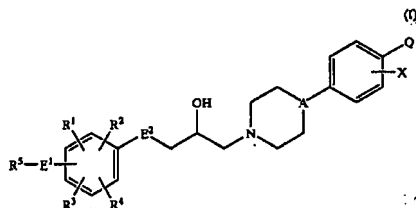
Applicants amended the claims in the amendment and reply dated July 14, 2006 and in the present response. The Office still has not performed the requisite analysis in view of the claim amendments. In fact, no analysis is made with regard to the claims. The Office only provides conclusions that the ‘470 patent claims are similar and obvious modifications of the instantly claimed subject matter. The Office fails to provide any analysis explaining why the instant claims fail to be independent and distinct from those of the ‘470 patent. For that reason alone, the rejection is improper and should be withdrawn. *See Kahn*, 441 F.3d at 988; *Lee*, 277 F.3d at 1343-44.

The Office’s reliance on *KSR* is inapposite. In particular, the Office provides no evidence or even relevant allegations regarding market demand. On point regarding the determination of obviousness of chemical compounds, the Federal Circuit recently held: “[The] test for *prima facie* obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*.” *Takeda Chem. Indus. Ltd. v. Alphapharm Pty. Ltd.*, 83

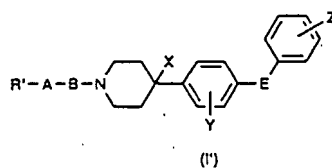
U.S.P.Q.2d 1169, 1174 (Fed. Cir. 2007). The Federal Circuit states the appropriate test: “structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness.” *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897, *en banc* (Fed. Cir. 1990). That is, in addition to structural similarity between the compounds, a *prima facie* case of obviousness also requires a showing of adequate support in the prior art for the change in structure. *In re Grabiak*, 769 F.2d 729, 731-32 (Fed. Cir. 1985) (reversing the Board, where the prior art provided no suggestion to substitute a sulfur atom for an oxygen atom). The prior art must suggest the specific molecular modifications necessary to achieve the claimed invention. *Takeda*, 83 U.S.P.Q.2d at 1174 (citing cases). The Office provides no such analysis in the present case, and the rejection thus should be withdrawn on this basis, as well.

(ii) **The present claims are not obvious over claims 1-10 of the ‘470 patent.**

The structure of formula (I') of the instant claims differs from formula (I) of the ‘470 patent claims. The two structures are depicted below:



Formula (I) of ‘470 Patent



Formula (I') of instant application

In Formula (I) of ‘470 patent claims, [E²] is O, S, or NR⁷; [E¹] is O, S, or NR⁶; and [R⁵] is H, an alkyl group, or an alkyl group substituted with a halogen. This means that [R⁵-E¹] may be a hydroxyl group or an alkoxy group, for example. When [E¹] is O or S, however, [E²] may not be O or S.

In the instant structure, R' may be:

- (1) a phenyl group, optionally substituted with a substituent selected from the group consisting of a halogen atom, a hydroxyl group, a C1-C5 optionally branched alkoxy group, and a C1-C5 optionally branched alkyl group optionally substituted with a halogen atom;

- (2) a phenoxy group, optionally substituted with a substituent selected from the group consisting of a halogen atom, a hydroxyl group, a C1-C5 optionally branched alkoxy group, and a C1-C5 optionally branched alkyl group optionally substituted with a halogen atom; or
- (3) a benzoyl group, optionally substituted with a substituent selected from the group consisting of a halogen atom, a hydroxyl group, a C1-C5 optionally branched alkoxy group, a C1-C5 optionally branched alkyl group optionally substituted with a halogen atom.

The present structure is not the same as Formula (I) of '470 patent claims. For example, the instant R' may be a phenoxy group, where the oxygen atom of the phenoxy group is bonded to [A-B]. In this case, [E²] of Formula (I) of '470 patent claims could be an oxygen. None of the possible optional substituents of the instant R', however, is found in Formula (I) of '470 patent claims. In particular, none of the instant substituents encompasses [R⁵-E¹] of Formula (I) of '470 patent claims. For example, as mentioned above [R⁵-E¹] may a hydroxyl group. The instant R' also may comprise a hydroxyl group substituent, for example. Claim 1 of the '470 patent, however, explicitly provides (emphasis added):

... when E¹ represents an oxygen atom or sulfur atom, E² **does not** represent an oxygen atom or a sulfur atom.

For that reason, R' substituted by a hydroxyl group is not encompassed by the '470 patent claims.

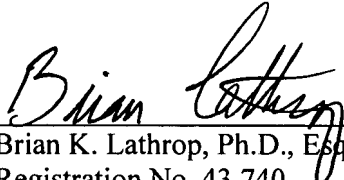
Accordingly, there is a structural difference between the presently claimed structure and the claimed compound in the '470 patent. The Office has not provided evidence to the contrary, nor has the Office provided—as it must—*reason or motivation* to make the presently claimed compound, in light of the claimed compound in the '470 patent. *See e.g., Dillon*, 919 F.2d 688, *Grabiak*, 769 F.2d at 731-32; *Takeda*, 83 U.S.P.Q.2d at 1174. The Office has provided nothing more than a conclusion of obviousness, which is improper. *See Kahn*, 441 F.3d at 988; *Lee*, 277 F.3d at 1343-44. The rejection accordingly should be withdrawn, and the application should be allowed.

CONCLUSION

In conclusion, this is believed to be in full response to the outstanding restriction requirement. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience. Should any outstanding fees be owed or overpayments credited, the Commissioner is invited to respectively charge or credit Deposit Account No. 50-0573. The Office is authorized to charge the Deposit Account for Notice of Appeal, if said Notice of Appeal is necessary in order to maintain pendency of the application.

Respectfully submitted,

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